

UTILITY PATENT APPLICATION TRANSMITTAL (Large Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Docket No.

262

Total Pages in this Submission

TO THE ASSISTANT COMMISSIONER FOR PATENTS

Box Patent Application
Washington, D.C. 20231

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled:

RADIALLY EXPANDABLE STENT FOR IMPLANTING IN A BODY VESSEL IN THE REGION OF A VESSEL BRANCH

and invented by:

Randolf VON OEPEN

If a CONTINUATION APPLICATION, check appropriate box and supply the requisite information:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: _____

Which is a:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: _____

Which is a:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: _____

Enclosed are:

Application Elements

1. ☒ Filing fee as calculated and transmitted as described below
2. ☒ Specification having 15 pages and including the following:
 - a. ☒ Descriptive Title of the Invention
 - b. ☐ Cross References to Related Applications (if applicable)
 - c. ☐ Statement Regarding Federally-sponsored Research/Development (if applicable)
 - d. ☐ Reference to Microfiche Appendix (if applicable)
 - e. ☒ Background of the Invention
 - f. ☒ Brief Summary of the Invention
 - g. ☒ Brief Description of the Drawings (if drawings filed)
 - h. ☒ Detailed Description
 - i. ☒ Claim(s) as Classified Below
 - j. ☒ Abstract of the Disclosure

Express Mail Mailing Label
Number EH 701277925 US
Date of Deposit May 14, 1998
I hereby certify that this paper or fee is being deposited
with the United States Postal Service "Express Mail
Post Office to Addressee" service under 37 CFR 1.10
on the date indicated above and is addressed to the:
Assistant Commissioner for Patents,
Washington, D.C. 20231.

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Application Elements (Continued)

3. ☒ Drawing(s) *(when necessary as prescribed by 35 USC 113)*

a. ☒ Formal Number of Sheets 3

b. ☐ Informal Number of Sheets _____

4. ☒ Oath or Declaration

a. ☐ Newly executed *(original or copy)* ☒ Unexecuted

b. ☐ Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional application only)*

c. ☒ With Power of Attorney ☐ Without Power of Attorney

d. ☐ DELETION OF INVENTOR(S)

Signed statement attached deleting inventor(s) named in the prior application,
see 37 C.F.R. 1.63(d)(2) and 1.33(b).

5. ☐ Incorporation By Reference *(usable if Box 4b is checked)*

The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

6. ☐ Computer Program in Microfiche *(Appendix)*

7. ☐ Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all must be included)*

a. ☐ Paper Copy

b. ☐ Computer Readable Copy *(identical to computer copy)*

c. ☐ Statement Verifying Identical Paper and Computer Readable Copy

Accompanying Application Parts

8. ☐ Assignment Papers *(cover sheet & document(s))*

9. ☐ 37 CFR 3.73(B) Statement *(when there is an assignee)*

10. ☐ English Translation Document *(if applicable)*

11. ☐ Information Disclosure Statement/PTO-1449 ☐ Copies of IDS Citations

12. ☐ Preliminary Amendment

13. ☒ Acknowledgment postcard

14. ☒ Certificate of Mailing

☐ First Class ☒ Express Mail *(Specify Label No.):* EH 701277925 US

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Accompanying Application Parts (Continued)

15. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*

16. ☐ Additional Enclosures *(please identify below):*

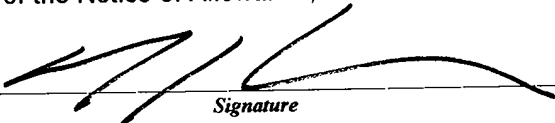
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Fee Calculation and Transmittal

CLAIMS AS FILED

For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	13	- 20 =	0	x \$22.00	\$0.00
Indep. Claims	1	- 3 =	0	x \$82.00	\$0.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
BASIC FEE					\$790.00
OTHER FEE (specify purpose)					\$0.00
TOTAL FILING FEE					\$790.00

- ☒ A check in the amount of \$790.00 to cover the filing fee is enclosed.
- ☒ The Commissioner is hereby authorized to charge and credit Deposit Account No. 19-4675 as described below. A duplicate copy of this sheet is enclosed.
- ☐ Charge the amount of _____ as filing fee.
- ☒ Credit any overpayment.
- ☒ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
- ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).


Signature

Dated: MAY 14, 1998

cc:

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864750" 95687060

BE IT KNOWN that I, *Randolf VON OEPEN*, citizen of Germany, whose post office address is Weiherweg 32, D-72145 Hirrlingen, Germany, have invented certain new and useful improvements in

*RADIALLY EXPANDABLE STENT FOR IMPLANTING
IN A BODY VESSEL IN THE REGION OF A VESSEL BRANCH*

of which the following is a complete specification:

BACKGROUND OF THE INVENTION

The present invention relates to a radially expandable stent for implanting in a body vessel in the region of a vessel branch, formed as a hollow-cylindrical element.

5 Radially expandable stents of the above mentioned general type are known in the art. The radial expandable stents are utilized at narrow locations in body vessels or body hollows for expanding the narrowing and stabilizing the vessel wall. Such narrowings of the body vessels can occur in the region of vessel branches. The use of a conventional stent is not possible here, since its wall would prevent a free blood circulation in the branched vessel. The German patent document DE 297 01 758.6 discloses a special stent which has a portion with increased radial openings so that this portion can extend over the branch location of the side branch vessel and no longer prevents the blood passage or hinders it only insignificantly. In the case of corresponding unfavorable stenosis formation of the main vessel directly in the branching region this stent however can not sufficiently cover the sickened vessel portion due to great radial openings extending over a whole portion.

10

15

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a radially expandable stent for implanting in a body vessel in the region of a vessel branch, which avoids the disadvantages of the prior art.

5 In keeping with these objects and with others which will become apparent hereinafter, one feature of present invention resides, briefly stated, in a radially expandable stent which has an increased radial opening and is premountable for implanting in the vessel on a balloon catheter, wherein the balloon catheter has a hollow chamber for passage of a guiding wire which extends in a center of the increased opening out of the hollow chamber and the stent.

10 Due to an increased opening in the stent wall, which can be located directly over the branching location, it is ensured that the total vessel wall is reliably protected by the stent. The increased opening has the purpose of guaranteeing the unobjectionable blood flow in the side branch vessel.

15 For accurate positioning of the stent however corresponding auxiliary means is needed. With the utilization of x-ray contrast means, the

exact positioning of an increased opening over the branch is not possible. Therefore, the inventive stent is premounted on a balloon catheter which has a hollow chamber for a guiding wire exiting through the increases opening. With the help of the guiding wire it is possible to position the great opening of the stent exactly over the exit of the side vessel. For this purpose, the catheter, by turning and displacing with the help of x-ray contrast means and visual monitoring on the x-ray screen, is manipulated until it is possible to introduce the second guide wire in the side branch vessel.

For insertion of the balloon catheter into the main vessel, the balloon catheter can be provided in a known manner with a hollow chamber extending along its longitudinal axis for a first guide wire exiting at the tip of the balloon catheter. It can be displaced along the guide wire without problems up to the vessel branch, before the use of the second guide wire for exact positioning of the increased opening. It is guaranteed that the catheter is exactly positioned, and then the balloon is inflated, and the stent is located on the vessel wall. Finally, the catheter can be pulled along the both guide wires from the vessel. The stent remains with the both wires in the vessel.

Via the guide wire of the side branch vessel a further balloon catheter can be inserted into the branch for further expansion around the

increased opening. Thereby it can be guaranteed that no wall part of the stent hinders the blood flow in the side branch vessel.

For forming the balloon catheter, various possibilities can be acceptable. For example, the hollow chamber for the guide wire which is guided from the increased opening can be formed by mounting a pipe on the balloon surface. This hollow chamber can be also formed by an intermediate space of a double-walled balloon. Also coating of a stretchable hose piece up to the balloon is possible, to provide a hollow chamber between this coated hose piece and the balloon for the guiding wire.

In an alternative embodiment, the balloon catheter can include three coaxially arranged hoses. Both inwardly located hoses can form a hollow chamber for receiving the both guiding wires.

The stent itself can be formed in different ways. It can have a multi-cellular wall and can be produced of a pipe. However, the stent can be also formed as a wire. In this case, it can be bent, twisted, knitted or textured from the wire. Advantageously, the increased opening is arranged in the center of the stent. However, also an eccentric arrangement of the increased opening can be realized for various applications.

5

The novel features which are considered as characteristic for the present invention are set forth in particular in the appended claims. The invention itself, however, both as to its construction and its method of operation, together with additional objects and advantages thereof, will be best understood from the following description of specific embodiments when read in connection with the accompanying drawings.

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BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic view showing three vessel branches with stenosis;

Figure 2 is a view showing a surface structure of a stent in accordance with the present invention; and

Figure 3 is a side view of a stent premounted on a balloon catheter.

DESCRIPTION OF PREFERRED EMBODIMENTS

Figure 3 shows three examples of typical stenoses which can occur in vessel branches. Figure 1a shows the stenosis 12 in a main vessel 10 before branching of a side branch vessel 11. In Figure 1b a very great stenosis 12' is located directly opposite to the branching of the side branch vessel 11. In Figure 1c it is located in a transition between the main vessel 10 and the side branch vessel 11.

In particular the stenosis shown in Figure 1b is covered only insufficiently with a bifurcation stent with a portion having increased radial openings. Exactly for such a case, the inventive stent can be suitable, as shown in Figures 2 and 3. Figure 2 shows the surface structure of a stent 20 which has a plurality of diamond-shaped radial openings 21 in stretch condition. A single, very large diamond-shaped openings 22 is formed in the central region of the stent 20. The opening 22 can be located in a body vessel exactly over the branching of a side branch vessel 11 shown in Figure 1.

In order to make possible the position-accurate placing of the stent 20, it is premounted on a balloon catheter 30 as shown in Figure 3. The balloon catheter 30 as shown in Figure 3 has a hollow chamber formed

in its interior and not shown in detail. A first guiding wire 31 passes through the hollow chamber of the balloon catheter 30. The stent 20 is pulled on the catheter 30 in the region of a balloon 32. A further hollow chamber 33 extends in the region of the balloon 32 for passing a second guiding wire 34.

5 In the region of the increased opening 22 the second guiding wire 34 exits from the hollow chamber 33 and from the stent 20. The guiding wire 34 is inserted in a side branch vessel 11 and serves as an adjusting aid for the positioning of the stent 20 in a body vessel 10. After pulling of the balloon catheter 30 from the vessel 10 it can also serve as a guiding wire for a further balloon catheter for expanding of the increased opening 22.

10 The shown embodiments of the balloon catheter 30 as well as the stent 20 are however only exemplary. The required hollow chamber 33 for passage of the second guiding wire 34 can be formed for example by a double-walled balloon 32 or two coaxial hose pieces. The shown stent 20 is cut from a tube. However, it can be also bent, knitted, twisted or
15 structured from a wire.

It will be understood that each of the elements described above, or two or more together, may also find a useful application in other types of constructions differing from the types described above.

While the invention has been illustrated and described as embodied in radially expandable stent for implanting in a body vessel in the region of a vessel branch, it is not intended to be limited to the details shown, since various modifications and structural changes may be made without departing in any way from the spirit of the present invention.

Without further analysis, the foregoing will so fully reveal the gist of the present invention that others can, by applying current knowledge, readily adapt it for various applications without omitting features that, from the standpoint of prior art, fairly constitute essential characteristics of the generic or specific aspects of this invention.

What is claimed as new and desired to be protected by Letters Patent is set forth in the appended claims.

CLAIMS

1 1. A device for implanting into a body vessel in the region of
2 a vessel branching, comprising a radially expandable stent formed as a
3 hollow cylindrical element and provided with an increase radial opening; and
4 a balloon catheter on which said stent is pre-mounted for implanting in the
5 vessel, said balloon catheter having a hollow chamber for passage of a
6 guiding wire so that it exits in a center of said increased opening from said
7 hollow chamber and said stent.

1 2. A device as defined in claim 1, wherein said balloon
2 catheter is provided with another longitudinal chamber extending along a
3 longitudinal axis of said catheter and formed so that a further guiding wire
4 exits at a tip of said balloon catheter.

1 3. A device as defined in claim 2, wherein said stent is
2 dilatable so that after a dilation of said stent, said balloon catheter is pullable
3 along said guiding wires out of the vessel.

1 4. A device as defined in claim 2, wherein said further guiding
2 wire is guided through said other hollow chamber out of said increased
3 opening.

1 5. A device as defined in claim 4, wherein said balloon
2 catheter has a balloon portion, said other hollow chamber for said further
3 guiding wire guided out of said increased opening being formed by a pipe
4 mounted on an outer surface of said balloon portion of said catheter.

1 6. A device as defined in claim 4, wherein said catheter has a
2 balloon portion which is formed as a double-walled balloon, said other hollow
3 chamber for guiding said further wire from said increase opening being
4 formed as an intermediate chamber of said double-wall balloon.

1 7. A device as defined in claim 4, wherein said balloon
2 catheter has a balloon portion, said other hollow chamber for guiding said
3 further wire out of said increased opening being formed as an intermediate
4 chamber between said balloon portion and a stretchable hose piece which
5 is pulled onto said balloon portion.

1 8. A device as defined in claim 2, wherein said balloon
2 catheter is composed of three coaxial hoses arranged so that two inwardly
3 located hoses form said hollow chambers for receiving said guiding wires.

1 9. A device as defined in claim 1, wherein said stent is
2 composed of a pipe and has a multi-cellular wall.

1 10. A device as defined in claim 1, wherein said stent is bent
2 from a wire.

11. A device as defined in claim 1, wherein said stent is
formed as a wire selected from the group consisting of structured wire,
knitted wire and twisted wire.

12. A device as defined in claim 1, wherein said increased
opening is arranged in a center of said stent.

13. A device as defined in claim 1, wherein said increased
opening is arranged eccentrically on said stent.

ABSTRACT OF THE DISCLOSURE

A device for implanting into a body vessel in the region of a vessel branching has a radially expandable stent formed as a hollow cylindrical element and provided with an increased radial opening, and a balloon catheter on which the stent is pre-mounted for implanting in the vessel, the balloon catheter having a hollow chamber for passage of a guiding wire so that it exits in a center of the increased opening from the hollow chamber and the stent.

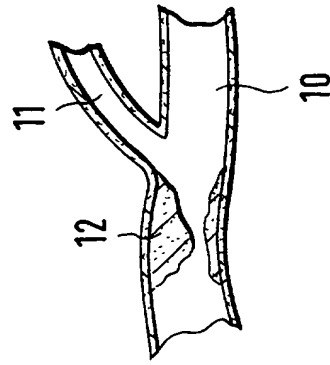


FIG. 1a

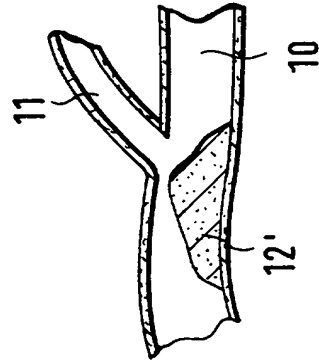


FIG. 1b

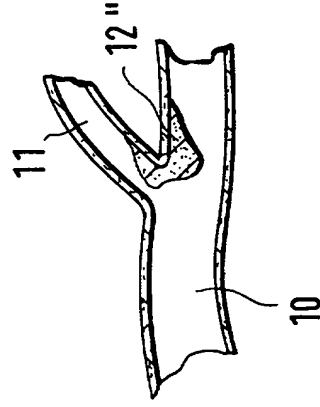


FIG. 1c

FIG. 2

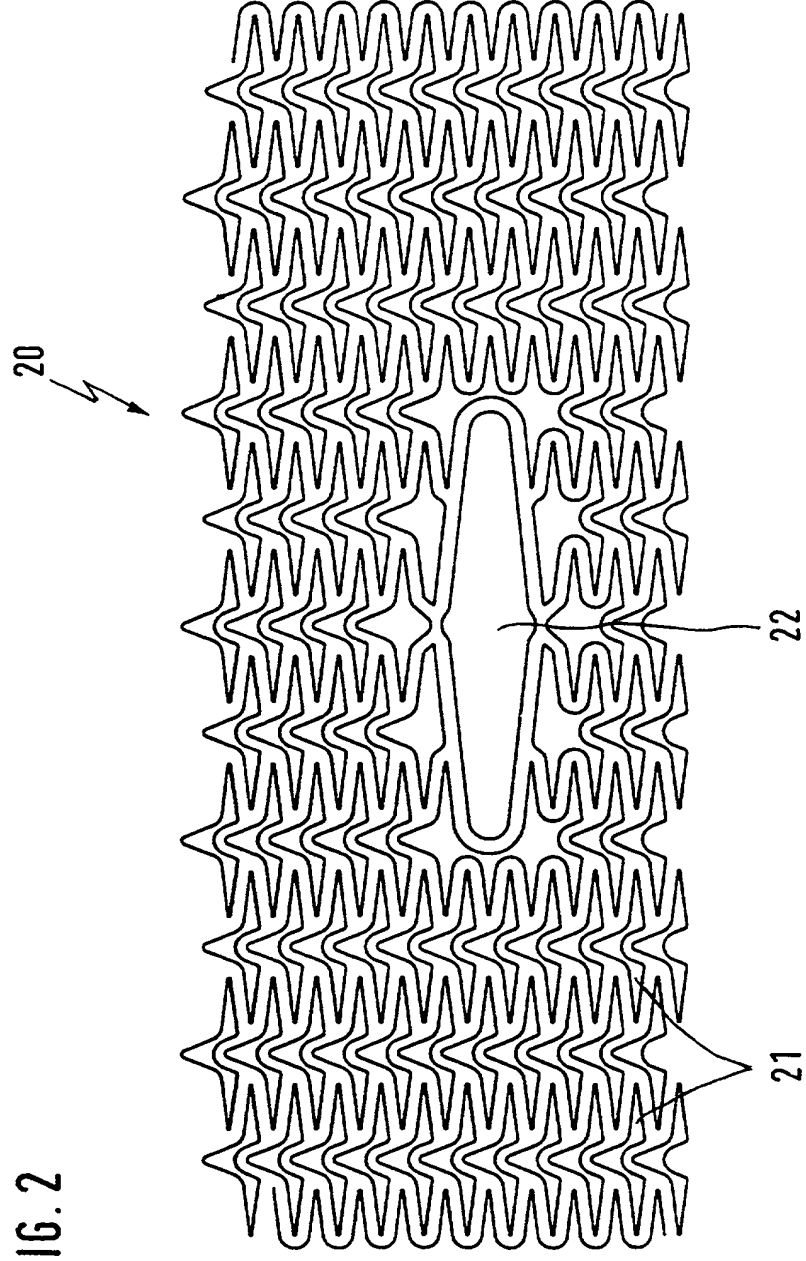
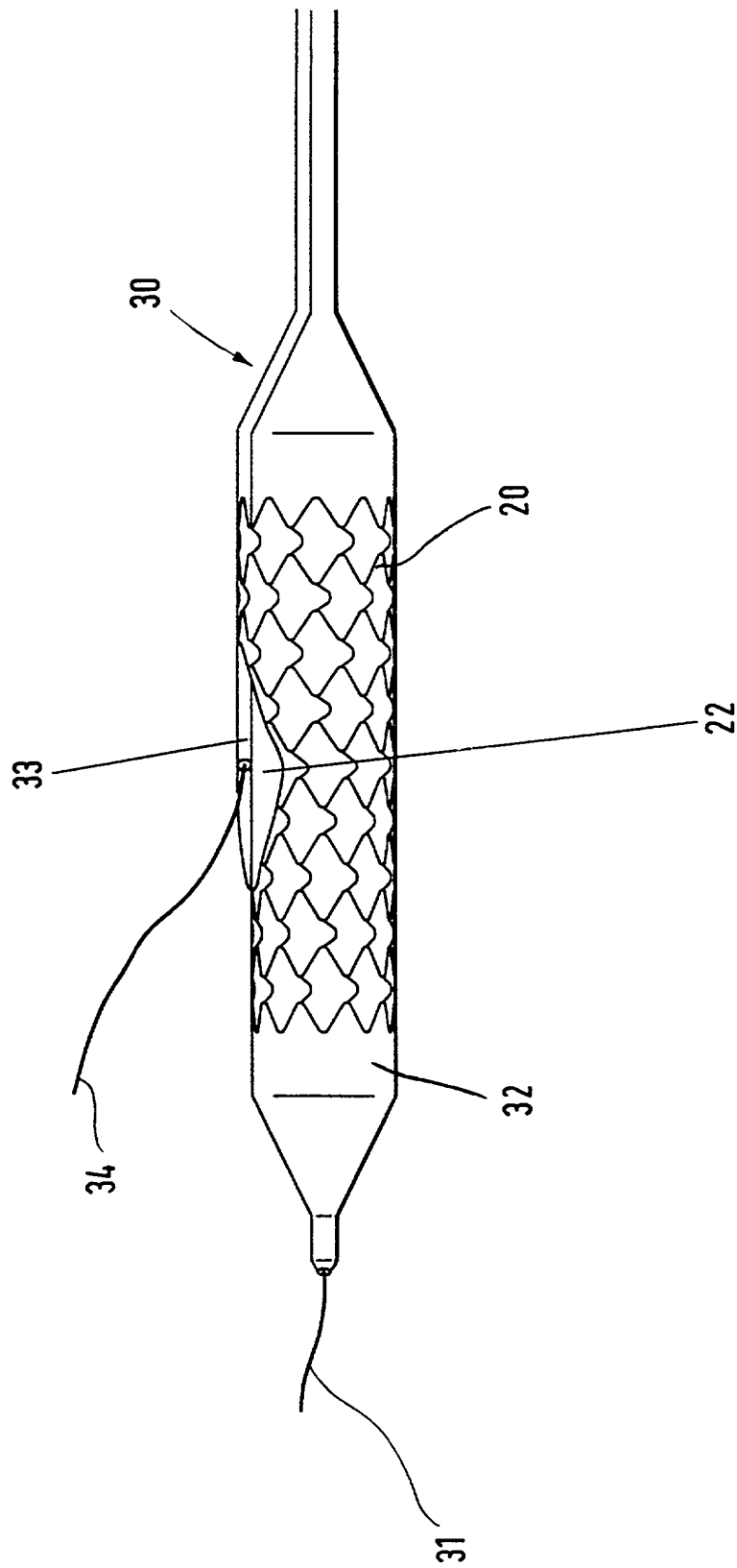


FIG. 3



COMBINED DECLARATION AND
POWER OF ATTORNEY

ATTORNEY DOCKET NO. 262

As a below-named inventor, I hereby declare that:

Randolf VON OEPEN

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention **RADIALLY EXPANDABLE STENT FOR IMPLANTING IN A BODY VESSEL IN THE REGION OF A VESSEL BRANCH** the specification of which:

(Check one) X is attached hereto.

 was filed on as
Application Serial No. and
was amended on
(if applicable)
was amended through
(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section § 119, of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s):

Priority Claimed

<u>297 08 803.3</u>	<u>DE</u>	<u>MAY 17, 1997</u>	<u>X</u>	<u> </u>
Priority Number	Country	Date filed (Priority Date)	Yes	No
<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Priority Number	Country	Date filed (Priority Date)	Yes	No
<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Priority Number	Country	Date filed (Priority Date)	Yes	No

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title

35, United States Code, Section 112, I acknowledge the duty to disclose material information as defined

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in Title 35, Code of Federal Regulations, Section 1.56(a), which occurred between the filing date of the prior application and the national or PCT International filing date of this application:

_____ (Application Serial No.)	_____ (Filing Date)	_____ (Status - Patented, pending, abandoned)
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_____ (Application Serial No.)	_____ (Filing Date)	_____ (Status - Patented, pending, abandoned)
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_____ (Application Serial No.)	_____ (Filing Date)	_____ (Status - Patented, pending, abandoned)
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that those statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of the application or any patent issued thereon.

The undersigned hereby authorizes **Michael J. Striker** and the firm of **Striker, Striker & Stenby**, to accept and follow instructions from:

MOEBUS SCHWAN WIESE

as to any action to be taken in the Patent and Trademark Office regarding this application without direct communication between Michael J. Striker, the firm of Striker, Striker & Stenby, and the undersigned. In the event of a change in the persons from whom instructions may be taken, Michael J. Striker and the firm of Striker, Striker & Stenby will be so notified by the undersigned.

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

POWER OF ATTORNEY: Michael J. Striker, Registration No. 27233

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Address all correspondence to: Striker, Striker & Stenby
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0007896 "0449
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Signature:	Date:	Residence and Full Postal Address: Weiherweg 32 72145 Hirrlingen Germany
Full Name of First or Sole Inventor: Randolf VON OEPEN	Citizenship: DE	
Signature:	Date:	Residence and Full Postal Address:
Full Name of Second Inventor:	Citizenship:	
Signature:	Date:	Residence and Full Postal Address:
Full Name of Third Inventor:	Citizenship:	
Signature:	Date:	Residence and Full Postal Address:
Full Name of Fourth Inventor:	Citizenship:	
Signature:	Date:	Residence and Full Postal Address:
Full Name of Fifth Inventor:	Citizenship:	
Signature:	Date:	Residence and Full Postal Address:
Full Name of Sixth Inventor:	Citizenship:	
Signature:	Date:	Residence and Full Postal Address:
Full Name of Seventh Inventor:	Citizenship:	
Signature:	Date:	Residence and Full Postal Address:
Full Name of Eighth Inventor:	Citizenship:	
Signature:	Date:	Residence and Full Postal Address:
Full Name of Ninth Inventor:	Citizenship:	